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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/643,270	08/19/2003	Peter Zahner		4070

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EXAMINER

MCCORMICK EWOLDT, SUSAN BETH

ART UNIT PAPER NUMBER

1654

DATE MAILED: 12/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/643,270	Applicant(s) ZAHNER, PETER	
	Examiner Susan B. McCormick-Ewoldt	Art Unit 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 November 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) 16-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election Restriction

Applicant's election with traverse of Group I in the reply filed on November 30, 2004 is acknowledged. The traversal is on the ground(s) that the numerous methods of protecting the skin from UVA/UVB rays aren't as specific as the claimed invention. This is not found persuasive because there are specific ingredients in other compositions that contain the claimed composition.

The requirement is still deemed proper and is therefore made FINAL.

Claims Pending

Claims 1-15 will be examined on their merits and claims 16-23 have been withdrawn from consideration.

Specification

The disclosure is objected to because of the following informalities: the term "erithema" is misspelled on page 1, lines 11 and 24. There are several punctuation errors through out the specification. Appropriate correction is required.

Claim Objections

Claim 8 is objected to because of the following informalities: There is no period at the end of the claim. In claim 11, the term "erythema" is spelled differently as in the specification. Claims 13 (line 2) and 14 (lines 1 and 2) are objected to because they are grammatically incorrect with the term "is" and "as". Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 7-8 and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 (a) is unclear in it's meaning of "(Bio) Melanin extract" since melanin is already an extract as stated in the specification (page 2). Also melanin is known to be extracted from a biological source so the added term "Bio" is redundant.

Claims 1 and 10 are rendered vague and indefinite by the terms "synergistically" and "synergistic" because the instant specification does not adequately disclose amounts and/or proportions of the claimed ingredients

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necessary to provide such a synergistic effect- i.e., the metes and bounds of this term are not clearly delineated because the instant specification fails to adequately teach synergistic amounts/proportions thereof (please note that synergism is well known in the art to be an unpredictable phenomenon highly dependent upon specific amounts and/or proportions of active ingredients therein).

Claims 7 and 8 recites the limitation "extract" in line 2. There is insufficient antecedent basis for this limitation in the claim because claim 6 states a "component".

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over de Rigal *et al.* (US 5,618,521) in view of McCook *et al.* (US 5,306,486) and Pawelek *et al.* (US. 5,618,519).

A sunscreen composition comprising a (Bio) Melanin extract, green tea and mineral pigments, is claimed.

de Rigal *et al.* expressly teach using a composition for suitably for screening UVA and/or UVB irradiation containing titanium dioxide and zinc oxide, which are metal oxide nanopigments at a concentration from 1-10% (column 3, lines 23-30, 55-60; column 4, lines 8-12 and claims 9, 16-17). In addition, de Rigal *et al.* disclose using green tea extract in the concentration between 0.1 to 2% by weight (column 2, lines 41-49; column 3, line 1 and claim 5). de Rigal *et al.* does not teach using Bio melanin in the composition.

McCook *et al.* disclose using green tea extract in a concentration ranging from 0.01 to 10% by weight and a sunscreen compound to inhibit UV absorption such as titanium dioxide or zinc oxide with the concentration ranging from 0.1 to 25% (column 2, lines 45-46, 60-61, 65-66; column 3, lines 1-2, 58-60 and claims 1-5).

Pawelek *et al.* disclose a composition that includes melanins to be used in a sunscreen (column 2, lines 35-37) and sources where melanin can be prepared (column 8, lines 39-41). In addition, Pawelek *et al.* teach that sun-screening agents can be added to the composition (column 7, lines 46-49).

Although McCook *et al.* and de Rigal *et al.* disclose using green tea extracts from 0.01 to 10% by weight and .1 to 2%, respectively, it was obvious to one skilled in the art to increase the amount of green tea extract hence, the greater amount of polyphenols (i.e. antioxidant) in the composition.

One of ordinary skill in the art would have been motivated to combine de Rigal *et al.* with McCook *et al.* and Pawelek *et al.* because de Rigal *et al.* with McCook *et al.*, both taught using green tea extract and titanium dioxide or zinc oxide for a composition that can be used as a sunscreen and Pawelek *et al.* taught that melanin used in a sunscreen compositions was advantageous. It is known in the art that titanium dioxide and zinc oxide provides photo-protective activity as stated in de Rigal *et al.* (column 3, line 55-60) and the amount of constituents claimed

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would be obvious in the claimed composition. Polyphenols are known in the art as an antioxidant which are an intrinsic characteristic of green tea which *Camellia oleifera* and *Camellia sinensis*.

It has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 220 F2d 454, 456, 105 USPQ 233; 235 (CCPA 1955). See MPEP § 2144.05 part II A. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to determine all operable and optimal concentrations of components because concentration is an art-recognized result-effective variable which would have been routinely determined and optimized in the pharmaceutical art.

It would clearly have been obvious to one of ordinary skill in the art at the time the claimed invention was made to use a composition made up of green tea extract, a UV ray blocking mineral pigment and melanin in an effective amount for a sunscreen composition, based upon the beneficial teaching provided by the cited references, as discussed above.

Summary

No claim is allowed.


Future Correspondence

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Susan B. McCormick-Ewoldt whose telephone number is (571) 272-0981. The Examiner can normally be reached Monday through Thursday from 6:00 a.m. to 4:30 p.m.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Bruce Campell, can be reached on (571) 272-0974. The official fax number for the group is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

sbme


PATRICIA LEITH
PRIMARY EXAMINER